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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,932	02/20/2004	Michael N. Helmus	BSCI-006/00US	9710
499 7590 04/14/2009 VIDAS, ARRETT & STEINKRAUS, P.A. SUITE 400, 6640 SHADY OAK ROAD EDEN PRAIRIE, MN 55344				
EXAMINER				
DESAI, ANAND U				
ART UNIT		PAPER NUMBER		
1656				
MAIL DATE		DELIVERY MODE		
04/14/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/781,932

**Applicant(s)**

HELMUS ET AL.

**Examiner**

ANAND U. DESAI

**Art Unit**

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5, 15-21, and 24-48 is/are pending in the application.
- 4a) Of the above claim(s) 3, 15-18, 20, 21, 24 and 33 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 25-27, 30, 34, 37, 38, 40, 43, 45 and 48 is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 5, 19, 28, 29, 31, 35, 36, 39, 41, 42, 44, 46 and 47 is/are rejected.
- 7) ☒ Claim(s) 19 and 32 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

#### **DETAILED ACTION**

1. This office action is in response to the amendment filed on February 2, 2009. Claims 8-14, 22, and 23 have been cancelled. New claims 39-48 have been added.
2. Claims 3, 15-18, 20, 21, 24, and 33 have been withdrawn previously.
3. Claims 1, 2, 4, 5, 19, 25, 26-32, and 34-48 are currently pending and are under examination.

#### **Withdrawal of Rejections**

4. The rejection of claim 19 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn based on the remarks describing the structure in dependent claim 20 and the objection cited below made for clarification purposes.
5. The rejection of claims 1, 4, 5, 25, 27-32, and 34-37 under 35 U.S.C. 102(b) as being anticipated by Mori et al. (JP 06128289) is withdrawn based on the amendment to the claims to recite a biocompatible polymer that is different from a bioactive polymer.
6. The rejection of claims 1, 4, 5, 25, 27-32, and 34-37 under 35 U.S.C. 102(e) as being anticipated by Zamora (U.S. Patent 7,297,343 B2) is withdrawn based on the remarks stating Zamora disclose a polysaccharide complexed not covalently bonded with the peptide and/or protein moiety.

## Pending Objections and Rejections

### *Claim Rejections - 35 USC § 103*

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1, 2, 4, 5, 19, 28-29, 31, 35-36, 39, 41-42, 44, and 46-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bellamkonda et al. (U.S. Patent 5,834,029; IDS document A2, September 1, 2005).

Bellamkonda et al. disclose a bioartificial three-dimensional hydrogel extracellular matrix derivatized with a cell adhesive peptide fragment that is provided for use in tissue regeneration or replacement. The peptide fragment contains the sequence TyrIleGlySerArg, and is covalently immobilized to the matrix. The matrix can be a polysaccharide, including agarose (see claims 5 and 6). It may be desirable to encapsulate the cell-seeded matrix in a semi-permeable membrane to form a bioartificial organ, including a nerve guidance channel. Various polymers and polymer blends can be used to manufacture the nerve guidance channel. Polymeric membranes forming the nerve guidance channel may include polyacrylates (including acrylic copolymers), polyvinylidenes, polyvinyl chloride copolymers, polyurethanes, polystyrenes, polyamides, cellulose acetates, cellulose nitrates, polysulfones, polyphosphazenes, polyacrylonitriles, poly(acrylonitrile/covinyl chloride), as well as derivatives, copolymers and mixtures thereof (see col. 7, lines 13-16, col. 12, lines 17-31, and claims 1-6).

The pending claims are interpreted to encompass a biomaterial consisting of SEQ ID NO: 16, whereas Bellamkonda disclose a peptide comprising SEQ ID NO: 16. It would have been obvious to the person having ordinary skill in the art to use a peptide consisting of SEQ ID NO: 16, because it was known in the art that YIGSR is a peptide with cell adhesion activity.

Therefore, it would have been obvious to the person having ordinary skill in the art to manufacture a biomaterial comprising SEQ ID NO: 16 covalently bonded to a polysaccharide, because Bellamkonda et al. discloses a peptide conjugated to a polysaccharide, agarose. The biomaterial disclosed by Bellamkonda et al. also comprises a biocompatible membrane that includes polyurethane.

***Claim Objections***

11. Claim 19 is objected to because of the following informalities: the Markush members describe the biocompatible polymer by a chemical structural feature, whereas the hydrogel is not described by a chemical structural feature. Suggest identifying the hydrogel using the chemical structural features recited in claim 20.
12. Claim 32 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Appropriate correction is required.

***Conclusion***

13. Claims 25-27, 30, 34, 37, 38, 40, 43, 45, and 48 are allowable.
14. Claims 19 and 32 are objected.
15. Claims 1, 2, 4, 5, 19, 28-29, 31, 35-36, 39, 41-42, 44, and 46-47 are rejected.
16. Claims 3, 15-18, 20, 21, 24, and 33 have been withdrawn previously.
17. This application contains claims 3, 15-18, 20, 21, 24, and 33 drawn to an invention nonelected. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.
18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANAND U. DESAI whose telephone number is (571)272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (517) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

April 12, 2009  
/ANAND U DESAI/  
Primary Examiner, Art Unit 1656